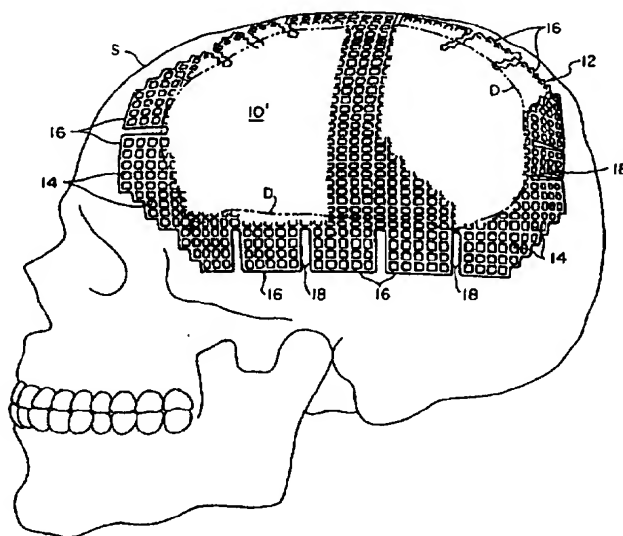




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(54) Title: CRANIOPLASTY PLATES AND METHOD OF INSTALLATION



(57) Abstract

A biocompatible cranioplasty plate structure (10'), and method of its installation, for use the surgical repair and recontour of large cranial defects of the human skull created or caused by injury, surgical intervention for tumor removal, or congenital anomaly or disease. The plate structure (10') is formed from a sheet of pliable perforated metallic material (12), and is of generally elliptical configuration with a central preformed arcuate and convex area matching the compound and complex curvature of the forehead, side or rear areas of the typical human adult skull. The plate structure includes adjustable peripheral panels (16) for bending fitment and close adaptation of the plate structure (10') to intact cranial bone of the skull adjacent to and surrounding the defect and for attachment of the plate structure to intact bone by bone screws.

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CRANIOPLASTY PLATES AND METHOD OF INSTALLATION

FIELD OF THE INVENTION

The present invention relates to perforated metallic plates for use in the surgical repair and recontour of the human skull following a depressed fracture, an intracranial operation
5 for tumor removal, or a penetrating missile injury, or to correct a congenital skull defect.

BACKGROUND OF THE INVENTION

One of the most conspicuous and psychologically
10 distressful after effects of a depressed fracture of the skull, an intracranial tumor operation, a penetrating missile injury, or life with a congenital skull deformity is a disfiguring skull defect. Frontal defects are usually unsightly and cause discomfort, especially when the patient bends forward. Also,
15 patients with large cranial defects feel insecure because of the brain's vulnerability to trauma.

In anatomic descriptions, the skull is commonly divided into: 1) the cranium or "braincase" which encloses the brain and is comprised of eight bones; and 2) the skeleton of the face
20 comprised of twelve paired bones. The eight bones that form the cranium include: the lower rear occipital bone, the sphenoid bone forming the back of the eye sockets, the ethmoid bone forming the inner part of the eye sockets, the frontal bone

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forming the forehead, the right and left side temporal bones, and the right and left side parietal bones contributing to the sides and base of the skull. The separate bones of the cranium are held together by immovable joints called sutures
5 found only between the skull bones.

When viewed from without, the cranium is generally spheroidal in shape which is divisible into six regions, namely,: "superior" (vertex or dome region), right and left "lateral", "posterior" (occipital bone region), "anterior"
10 (frontal bone region), and "inferior" (base region). Viewed from above, the skull is oval in outline (wider behind than in front) and defined by the right and left side parietal bones, the greater part of the frontal bone, the distal portions or wings of the sphenoid bone, the right and left temporal bones,
15 and the lower rear occipital bone. The arcuate and convex shaped areas encompassing: 1) the anterior frontal bone, 2) the right and left side parietal and temporal bones, and 3) the occipital bone and posterior portions of the right and left side parietal bones are reasonably alike in size and curvature for
20 the typical adult human males and for the typical adult human females. These skull areas form the principal fields for the occurrence of depressed fractures, penetrating missile injuries, and intracranial tumor surgical procedures. Such areas also form the principal fields for the surgical correction of
25 congenital skull defects.

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Various cranioplasty methods and materials have been employed over many years for the repair of skull defects.

A satisfactory cranioplasty procedure should employ an onlay technique with a simple method of attachment of the prosthesis to the skull. The material used should be biologically inert with respect to the tissues it contacts, radiolucent, easily and accurately shaped to the normal skull contour in the area of application, capable of being adjusted at the time of application, and it should have sufficient mechanical strength to resist fracture or deformation under severe impact loading.

After World War I autogenous bone grafts, taken from the iliac crest, were used as the material of choice for cranioplasty procedures. A major operation was required to obtain the graft for a large skull defect and the patients often had more postoperative pain from the donor site than from the actual grafted skull area. Further, reproduction of the appropriate skull contour often proved to be difficult.

Following World War II some skull defects were repaired through the use of autopolymerized acrylic resin plates. Initially, such cranioplasty plates were preformed from a template or impression made at the time of a first operation. Later, form-fitting plastic cranioplasty procedures were tried in which the plastic material was molded into the skull defect during the plastic hardening process - the hardening process frequently releasing excess heat both to the patient at the

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cranioplasty site and to the hands of the surgeon shaping the material within the defect. Again, with larger defects, it was found to be difficult to shape and appropriately contour the cranioplasty material.

5 Metals and metal alloys, including tantalum, titanium, stainless steel, and chromium-cobalt, have not been widely used because of the difficulty in forming the cranioplasty plate to the compound and complex curvatures of the skull. Tantalum cranioplasty plates have been shaped by die swaging techniques
10 or by hammering tantalum plate material into a counter die.

For treating small skull defects the use of plastic or metal cranioplasty plates or bone-grafting techniques have usually proved satisfactory. The larger skull defect, however, has posed the special problem of matching cranioplasty
15 plates to skull contours and of fixation of such plates to adjacent skull bone structures.

It is a principal object of the present invention to provide perforated titanium cranioplasty plates for the surgical repair and recontour of large defects of the human skull.

20 It is a further object of the invention to provide perforated titanium cranioplasty plates for the surgical repair and recontour of large defects of the human adult skull with such plates having a central preformed convex area matching the compound and complex curvatures of forehead, side and rear areas
25 of the typical human adult skull.

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It is a still further object of the invention to provide perforated titanium cranioplasty plates for the surgical repair and recontour of large defects of the human adult skull with such plates having a central preformed convex area matching the compound and complex curvatures of the forehead, side and rear areas of the typical human adult skull and having adjustable (pliable) peripheral panels for fitment and attachment of the plates to normal cranial bone structures adjacent the defects.

Other objects and advantages of the invention will become apparent from the following summary and detailed descriptions of the preferred embodiments of the invention taken in conjunction with the accompanying drawing figures.

SUMMARY OF THE INVENTION

The present invention relates to improved metallic cranioplasty plates for use in the surgical repair and recontour of large cranial defects of the human skull resulting from a depressed fracture of the skull, an intracranial tumor removal operation, a penetrating missile injury to the skull, or a congenital skull deformity. More specifically, the invention relates to the provision of large cranioplasty plates fabricated from relatively thin perforated, biologically inert, titanium sheet material having a shape and size sufficient to completely cover the cranial defect area and including pliable slotted peripheral attachment panels for final contouring and

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fitment of the plates to the skull for close cranial adaptation thereto.

The perforated titanium cranioplasty plates of the invention include a preformed arcuate and convex central area within the confines of the pliable peripheral attachment panels. The convex central areas of the plates are of a size and curvature shape which reasonably match the spheroidal shape and size of the skulls of the majority of adult human male patients and adult human female patients. Thus, the arcuate and convex shaped central areas of the plates are particularly unique in their applicability to the repair and recontour of the majority of large cranial defects in adult humans in four principal skull areas encompassing: 1) the frontal bone of the skull; 2) the right side parietal and temporal bones of the skull; 3) the left side parietal and temporal bones; and 4) the occipital bone and posterior portions of the right and left side parietal bones. These four skull areas form the principal cranial fields for the occurrence of depressed features, penetrating missile injuries, and intracranial tumor removal surgical procedures. Such areas also form the principal cranial fields requiring surgical correction of large congenital skull defects.

The implantable metallic cranioplasty plates of the invention are fabricated from thin sheets of commercially pure titanium or titanium alloys (finished thickness in the range of

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about 0.5 mm to about 1.5 mm) and preferably comprise mesh sheets which include uniform rows and lines of circular or square perforations for receiving titanium bone screws having low profile heads. The plate and panel perforations are
5 created by techniques that result in the finished plates being free of mechanically induced stresses as are normally created by metal stamping, forging and mechanical machining procedures and techniques. The central convex preformed areas of the plates of the invention are created by the forming of such plate
10 areas over dies which closely approximate the normal curvature areas of the skulls of human adult males and females as defined hereinbefore. The use of perforated titanium sheet mesh material with uniform lines and rows of square holes is preferred since the cranioplasty plates with square holes
15 provide the surgeon with an implantable plate material which can be easily shaped or bent in the pliable peripheral panel areas to conform to the cranial bone surrounding the cranial defect without inducing mechanical stresses into the material. Also, the square hole perforated titanium sheet material of the
20 plates in the peripheral panel areas can be easily cut or trimmed to fit the skull contour surrounding the defect site without leaving jagged plate edges. Another preferred form of perforated titanium (or titanium alloy) sheet material is comprised of a gridwork of legs which form repeating patterns of
25 rectangular or triangular open spaces.

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The implantable perforated titanium cranioplasty plates of the invention are radiolucent whereby the use of X-ray, CT and MRI examination of the skull behind the plates is not precluded or blocked and no imaging artifacts are created.

5 Further, the perforated cranioplasty plates of the invention allow desired bio-fluid flow from side-to-side through the plates after their surgical placement and covering by outer soft tissues.

BRIEF DESCRIPTION OF THE DRAWING FIGURES

10 FIG. 1 is a top plan view of a perforated (square hole mesh) titanium cranioplasty plate preform of the present invention in its planer form prior to the application of anatomical convex shaping of the plate in its central skull defect covering area and prior to final adjustment contouring of
15 the peripheral attachment panels of the plate during surgery for final fitment of the plate panels to normal cranial bone structures adjacent the skull defect;

FIG. 2 is a side (lateral) view of a human skull showing the perforated metallic cranioplasty plate of FIG. 1
20 anatomically contoured and provided with adjusted slotted peripheral attachment panels for close cranial adaptation to cover and protect a large defect in the temporal and parietal bones on the left side of the skull;

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FIG. 3 is a front and top (frontal) perspective view of a human skull showing a perforated (square hole mesh) metallic cranioplasty plate of the invention anatomically contoured for close cranial adaptation to cover and protect a large defect in the frontal bone of the skull;

FIG. 4 is a plan view of a section of perforated metallic grid material of rectangular opening configuration applicable for use in forming cranioplasty plates in accordance with the present invention; and

FIG. 5 is a plan view of a section of perforated metallic grid material of triangular opening configuration (isogrid material) applicable to use in forming cranioplasty plates in accordance with the invention.

DETAILED DESCRIPTION OF THE INVENTION

Referring to FIG. 1 of the drawing sheets there is illustrated a metallic cranioplasty plate preform 10 of the present invention. The plate preform 10 has been configured for shaping into an appropriately contoured cranioplasty plate for application over a large cranial defect encompassing contiguous areas of the left side parietal and temporal bones of the human skull. The plate preform, of generally elliptical shape, is formed of a pliable sheet 12 of commercially pure titanium (or titanium alloy) which has been perforated with uniform rows and lines of square holes 14.

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The preform 10 includes peripheral plate attachment panels 16 which are separated from one another by slots 18. Thus such panels may be easily shaped or bent, and trimmed, to conform to the cranial bone characteristics and curvatures surrounding the cranial defect which is to be protected by the finished and installed cranioplasty plate with the installed plate providing the desired restored contour of the skull throughout the area of the cranial defect.

In FIG. 2 there is illustrated a side (lateral) view of a human skull S showing a finished perforated metallic cranioplasty plate 10' formed from the plate preform 10 of FIG. 1. The preform plate 10 has been anatomically contoured for fitment to the skull over the contiguous cranial defect area encompassing the left side parietal and temporal bones and the peripheral attachment panels 16, separated from one-another by slots 18, have been bent inwardly as required to assure close fitment of the finished cranioplasty plate 10' to the skull. In the FIG. 2 illustration, bone screws have not been selectively applied through the square hole perforations of the attachment panels 16 for affixation of the cranioplasty plate prosthesis to the skull. Further, in FIG. 2 the shape of the cranial defect area D is shown in dashed outline.

In FIG. 3 there is illustrated a front and top (frontal) perspective view of a human skull S' showing a finished perforated metallic cranioplasty plate structure 20' of the

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invention, the plate structure 20' having been formed from a plate preform 20 (not illustrated) of generally elliptical shape similar to the plate preform 10 of FIG. 1. The plate preform for the cranioplasty plate structure 20', formed of a pliable sheet 22 of commercially pure titanium with square hole perforations 24, has been anatomically contoured for fitment to the skull S' over a cranial defect area encompassing the frontal bone of the skull. The peripheral attachment panels 26 of the plate structure 20', separated from one-another by slots 28, have been bent inwardly as required to assure close fitment of the finished cranioplasty plate to the skull. In the FIG. 3 illustration, bone screws have not been selectively applied through the square hole perforations of the attachment panels 26 for affixation of the cranioplasty plate structure to the skull.

FIG. 4 is a plan view of a section of perforated metallic sheet material 30 comprised of a gridwork of legs 32 which form repeating patterns of rectangular open spaces 34, such material being applicable to use in forming cranioplasty plates in accordance with the present invention. The terminal ends of the legs 32 meet at, and are joined in, grid corners 36 which include holes 38 through which bone screws may be applied to affix the material to health bone at the periphery of a cranial defect. FIG. 5 is a plan view of a section of perforated metallic sheet material 40 comprised of a gridwork of legs 42 which form repeating patterns of triangular open spaces

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44, such material also being applicable to use in forming cranioplasty plates in accordance with the invention. The terminal ends of the legs 42 meet at, and are joined in, grid corners 46 which include bone screw holes 48.

5 It is to be understood that the cranioplasty plates of the present invention are formed from a series of pliable metallic preforms (formed of biologically inert, commercially pure titanium or titanium alloy sheet material) which may be comprised of meshes having uniform parallel rows and perpen-
10 dicularly oriented uniform lines of square hole or circular hole perforations or which are formed with repeating patterns of rectangular or triangular open gridwork. Preferably, such mesh perforations range in size from about 0.5 mm to about 3.0 mm in side dimension or diameter, respectively. The open
15 spaces of the gridwork sheet material have defining legs which range in lengths from 3.0 mm to 8.0 mm or more. Also, the finished thickness of such preforms is in the range of from about 0.5 mm to about 1.5 mm and the preforms are of generally elliptical shape. They are provided with like perforated
20 peripheral attachment panels separated from one-another by slots so that the edge portions of the finished cranioplasty plate can be shaped by the cranial surgeon at the time of plate application and fitment for recontour, closure and protection of a large cranial defect.

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The perforated titanium cranioplasty plates of the invention include a preformed arcuate and convex central area within the confines of the pliable peripheral panels. The convex central areas of the plates are of a size and curvature shape which reasonably match the spheroidal shape and size of the majority of the skulls of adult human males and adult human females. Thus, the arcuate and convex shaped central areas of the plates are particularly unique in their particular applicability to the repair and recontour of the majority of large cranial defects in adult humans in four principal skull areas, i.e., spheroidal skull areas which encompass:

- 1) the frontal bone of the skull structure;
 - 2) the contiguous areas of the right side parietal and temporal bones of the skull;
 - 3) the contiguous areas of the left side parietal and temporal bones of the skull; and
 - 4) the contiguous areas of the occipital bone and posterior portions of the right and left side parietal bones.
- These four skull areas comprise the principal cranial fields for the occurrence of depressed fractures, penetrating missile injuries, and intracranial tumor removal surgical procedures. Such areas also form the principal cranial fields requiring surgical correction of large congenital skull defects.

As previously indicated, the plate and panel perforations of the cranioplasty plates of the invention are created in

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the flat titanium (or titanium alloy) plate preforms by techniques that result in the finished plates being free of mechanically induced stresses as are normally created by metal stamping, forging and mechanical machining procedures and techniques. The central arcuate and convex preformed areas of the plates of the invention are created by forming of the plate preforms in their central areas over dies which closely approximate the normal four curvature areas of the typical skulls of adult males and females as defined hereinbefore.

The use of perforated titanium (or titanium alloy) sheet material with square holes is preferred since the cranioplasty plates with square holes provides the cranial surgeon with an implantable plate material which can be easily shaped or bent in the pliable peripheral panel areas to conform to the intact cranial bone surrounding the cranial defect area without inducing mechanical stresses into the material. Also, the square hole perforated titanium sheet material of the plates in the peripheral panel areas can be easily cut or trimmed to fit the skull contour surrounding the defect site without leaving jagged plate edges.

The implantable perforated titanium cranioplasty plates of the invention are radiolucent whereby the use of X-ray, CT and MRI examination of the repaired skull behind the plates is not precluded or blocked and no imaging artifacts are created. Further, the perforated cranioplasty plates of the invention

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allow desired bio-fluid flow from side-to-side through the plates after their surgical placement covering of the defect, attachment to the intact bone surrounding the defect, and covering by outer soft tissues.

5 While the invention has been described in connection with particular cranioplasty plate structures for use in the surgical repair and recontour of large cranial defects of the human skull, many modifications of the invention will be apparent to those skilled in the art. Accordingly, such
10 modifications are to be included within the spirit and scope of the invention as defined by the following claims.

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What is claimed is:

1. A biocompatible cranioplasty plate structure for use in the surgical repair and recontour of a large cranial defect of the human skull created or caused by injury, surgical
5 intervention for tumor removal, or congenital anomaly or disease, said plate structure comprising a sheet of pliable perforated metallic material of generally elliptical configuration,

10 said plate structure including a central preformed arcuate and convex area matching the compound and complex curvature of the forehead, side or rear areas of the typical human adult skull, and

15 said plate structure including adjustable peripheral panels for bending fitment and close adaptation of said plate structure to intact cranial bone of the skull adjacent to and surrounding the defect and for attachment of said plate structure thereto by bone screws having low profile heads and applicable through perforations of said panels and into said surrounding intact cranial bone.

20 2. A biocompatible cranioplasty plate structure as claimed in claim 1 wherein the sheet of pliable, perforated metallic material is a mesh sheet fabricated of biologically inert, commercially pure titanium or titanium alloy material

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having a thickness in the range of about 0.5 mm to about 1.5 mm and includes uniform parallel rows and uniform parallel lines of perforations, said parallel lines of perforations being arranged generally perpendicular to said parallel rows of perforations.

5 3. A biocompatible cranioplasty plate structure as claimed in claim 2 wherein said mesh sheet includes perforations selected from the group consisting of square holes and circular holes.

10 4. A biocompatible cranioplasty plate structure as claimed in claim 1 wherein the sheet of pliable, perforated metallic material is a gridwork sheet fabricated of biologically inert, commercially pure titanium or titanium alloy material having a thickness in the range of about 0.5 mm to about 1.5 mm and includes legs which define repeating patterns of rectangular
15 open spaces, the terminal ends of said legs meeting at, and joined in, grid corners which include holes through which bone screws may be applied.

20 5. A biocompatible cranioplasty plate structure as claimed in claim 4 wherein the legs of said gridwork sheet which define repeating patterns of rectangular open spaces range in lengths from about 3.0 mm to about 8.0 mm.

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6. A biocompatible cranioplasty plate structure as claimed in claim 1 wherein the sheet of pliable, perforated metallic material is a gridwork sheet fabricated of biologically inert, commercially pure titanium or titanium alloy material having a thickness in the range of about 0.5 mm to about 1.5 mm and includes legs which define repeating patterns of triangular open spaces, the terminal ends of said legs meeting at, and joined in, grid corners which include holes through which bone screws may be applied.

7. A biocompatible cranioplasty plate structure as claimed in claim 6 wherein the legs of said gridwork sheet which define repeating patterns of triangular open spaces range in lengths from about 3.0 mm to about 8.0 mm.

8. A biocompatible cranioplasty plate structure for onlaid use in the surgical repair and recontour of a large cranial defect of the adult human skull created or caused by injury, surgical intervention for tumor removal, or congenital anomaly or disease, said plate structure comprising a pliable perforated mesh sheet of biologically inert, commercially pure titanium or titanium alloy of generally elliptical configuration,

said perforated mesh sheet having a thickness in the range of about 0.5 mm to about 1.5 mm and including uniform

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parallel rows and uniform parallel lines of perforations, said parallel lines of perforations being arranged generally perpendicular to said parallel rows of perforations,

5 said plate structure including a central preformed arcuate and convex area matching the compound and complex curvature of the forehead, side or rear areas of the typical human adult skull, and

10 said plate structure including a series of adjustable peripheral panels, extending radially from said central preformed area and separated from one-another by radial slots, for bending fitment and close adaptation of said plate structure to intact cranial bone of the skull adjacent to and surrounding said cranial defect and for attachment of said plate structure thereto by bone screws applicable through perforations of said
15 panels and into said surrounding intact cranial bone.

9. A biocompatible cranioplasty plate structure as claimed in claim 8 wherein said perforated titanium sheet includes perforations of the type selected from the group consisting of square holes and circular holes.

20 10. A cranioplasty method for the surgical repair and recontour of a large cranial defect area in the forehead, side or rear of the adult human skull created or caused by injury, surgical intervention for tumor removal, or congenital anomaly or disease comprising:

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a) surgically reflecting the soft scalp tissues covering said cranial defect area;

b) surgically installing an onlay biocompatible cranioplasty plate structure comprised of a pliable sheet of biologically inert perforated titanium or titanium alloy of generally elliptical configuration, said plate structure including a central preformed arcuate and convex area matching the typical compound and complex curvature of the forehead, side or rear areas of said skull in said defect area, and said plate structure including a series of adjustable peripheral panels for fitment of said plate structure to intact cranial bone of said skull adjacent to and surrounding said defect area and for attachment of said plate structure to said intact cranial bone;

c) bending said peripheral panels as required to obtain close adaptation of said plate structure to said intact cranial bone and to position said plate structure for recontour of said skull in said defect area;

d) fastening said plate structure to said skull by bone screws applied through perforations of said panels and into the intact cranial bone surrounding said defect area; and

e) covering said plate structure with the soft scalp tissues reflected from said defect area.

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AMENDED CLAIMS

[received by the International Bureau on 14 October 1997 (14.10.97);
original claims 1-10 replaced by new claims 11-31 (5 pages)]

11. A cranioplasty plate for use in the repair and
recontour of large cranial defects in the human skull,
comprising:

- 5 a sheet of perforated metallic material having a
central portion and at least one peripheral panel;
said central portion formed to define substantially
rigid arcuate and convex areas configured to approximate the
normal bone structure of a large cranial defect and to
10 protect underlying tissue; and
said at least one peripheral panel substantially less
rigid than said central portion, said peripheral panel for
bending fitment of said sheet to bone surrounding the
cranial defect.

- 15 12. The apparatus of claim 11 wherein said sheet is
fabricated of commercially pure titanium or titanium alloy
material.

13. The apparatus of claim 11 wherein said central
portion includes compound curves matching a large area
20 cranial defect.

14. The apparatus of claim 11 wherein said sheet is a
gridwork sheet fabricated of biologically inert,
commercially pure titanium or titanium alloy material having
a thickness in a range of about 0.5mm to about 1.5mm and
25 includes legs which define repeating patterns of rectangular
open spaces, the terminal ends of said legs meeting at, and
joined in, grid corners which include holes adapted to
receive screws.

AMENDED SHEET (ARTICLE 19)

15. The apparatus of claim 14 wherein said legs of said gridwork sheet define repeating patterns of rectangular open spaces ranging in length from about 3.0mm to about 8.0mm.

5 16. The apparatus of claim 11 wherein said sheet is a gridwork sheet fabricated of biologically inert, commercially pure titanium or titanium alloy material having a thickness in the range of about 0.5mm to about 1.5mm and includes legs which define repeating patterns of triangular
10 open spaces, the terminal ends of said legs meeting at, and joined in, grid corners which include holes adapted to receive screws.

17. The apparatus of claim 11 wherein:
said central portion is contoured to approximate a
15 frontal bone of the human skull structure.

18. The apparatus of claim 11 wherein:
said central portion is contoured to approximate a contiguous area of the right side parietal and temporal bones of the human skull.

20 19. The apparatus of claim 11 wherein:
said central portion is contoured to approximate a contiguous area of the left side parietal and temporal bones of the human skull.

25 20. The apparatus of claim 11 wherein:
said central portion is contoured to approximate a

contiguous area of the occipital bone and posterior portions of the right and left side parietal bones.

21. A biocompatible cranioplasty plate structure for onlaid use in the surgical repair and recontour of a large
5 cranial defect of the human skull, said plate structure comprising:

a perforated mesh sheet of biologically inert, commercially pure titanium or titanium alloy of generally elliptical configuration;

10 said mesh sheet including a central preformed arcuate and convex substantially rigid plate area contoured to approximate the compound and complex curvature of the forehead, side or rear areas of the typical human skull; and

15 said mesh sheet including at least one adjustable peripheral panel substantially less rigid than said central plate area, said peripheral panel for bending fitment and close adaptation of said mesh sheet to intact cranial bone of the skull adjacent to and surrounding said cranial defect.

20 22. The apparatus of claim 21, wherein said mesh sheet has a thickness in the range of about 0.5mm to about 1.5mm and including uniform parallel rows and uniform parallel lines of perforations, said parallel lines of perforations being arranged generally perpendicular to said
25 parallel rows of perforations,

23. A method for forming an implantable cranioplasty plate with an adjustable peripheral portion, comprising:
providing a pliable metallic sheet and a die having a

contoured area corresponding to a portion of the human skull;

aligning said pliable metallic sheet with said die, a peripheral portion of said sheet extending beyond said
5 contoured area of said die; and

exerting a force on said metallic sheet to deform the pliable metallic sheet into contact with the contoured area of the die, whereby deformation of said sheet creates a rigid central area of said implant while the peripheral
10 portion outside said die remains pliable.

24. The method of claim 23 wherein said die is contoured to approximate the frontal bone of the skull.

25. The method of claim 23 wherein the die is contoured to approximate the contiguous area of the right
15 side parietal and temporal bones of the skull.

26. The method of claim 23 wherein the die is contoured to approximate the contiguous area of the left side parietal and temporal bones of the skull.

27. The method of claim 23 wherein the die is
20 contoured to approximate the contiguous area of the occipital bone and posterior portions of the right and left side parietal bones.

28. The method of claim 23 wherein said pliable metallic sheet is fabricated of commercially pure titanium
25 and includes perforations.

29. The method of claim 23 wherein said pliable metallic sheet is fabricated of commercially pure titanium alloy and includes perforations.

30. The method of claim 23, wherein said peripheral
5 portion includes at least two separate peripheral portions.

31. The method of claim 23, wherein the die contoured area includes compound curves matching large areas of the human cranium.

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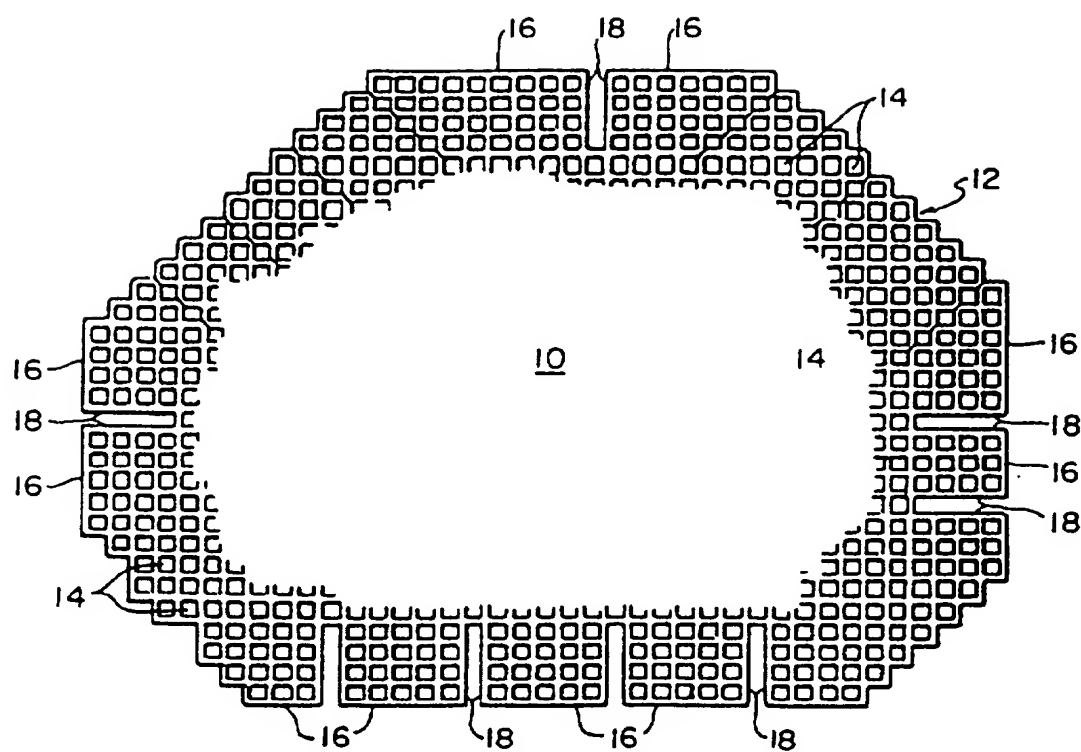
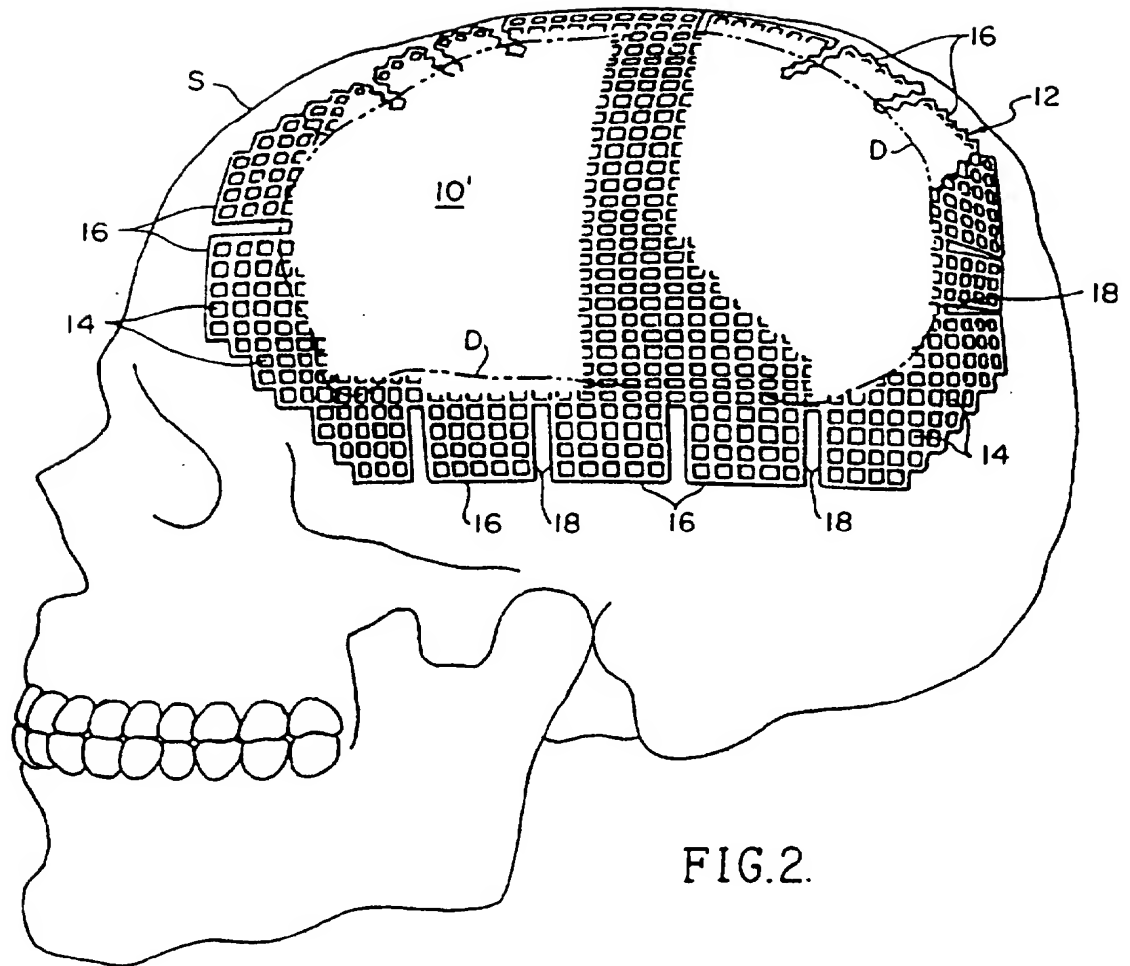


FIG. 1.

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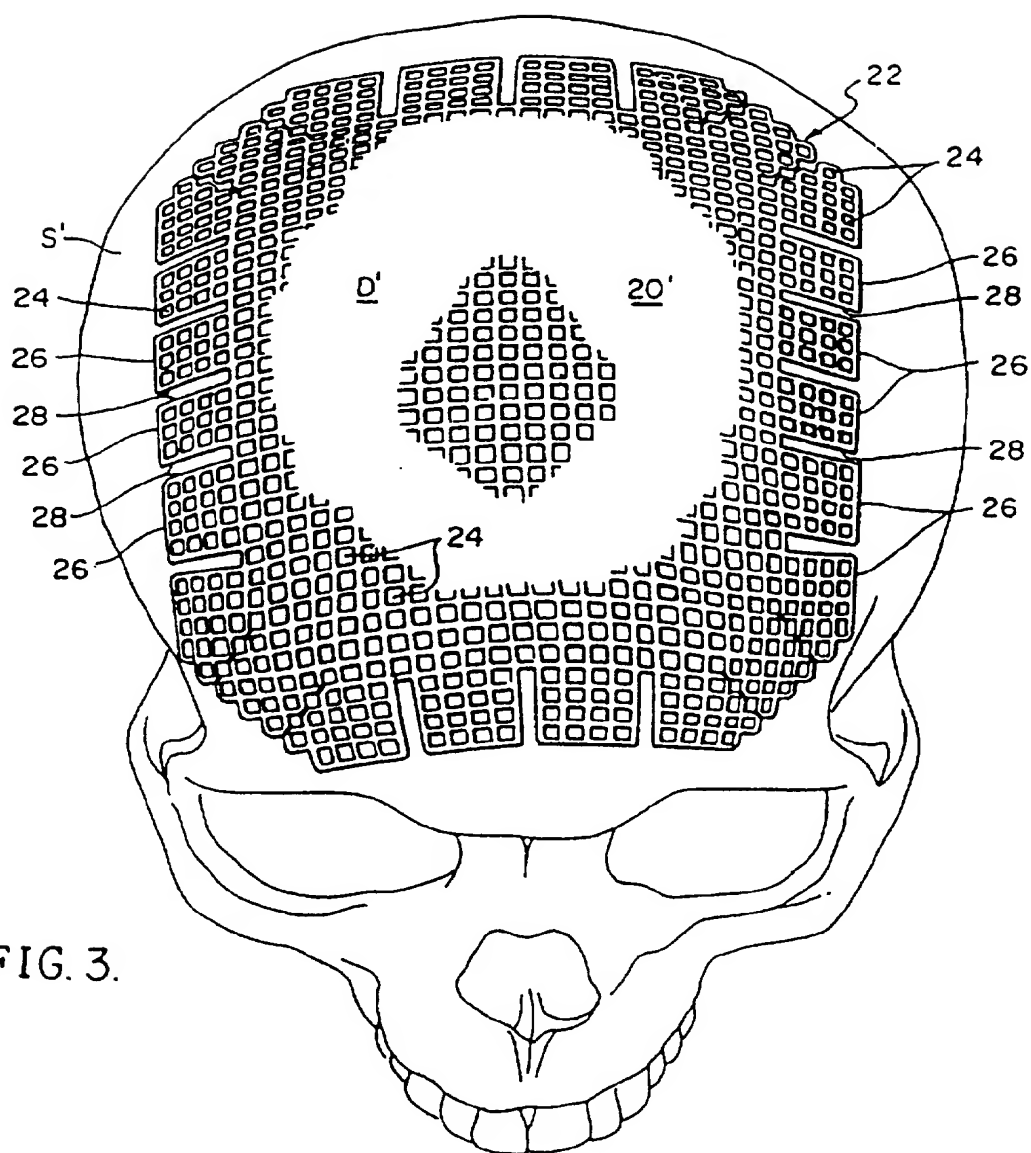


FIG. 3.

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FIG. 4.

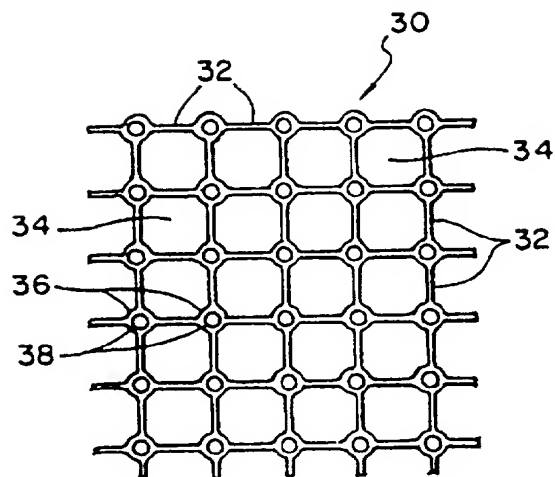
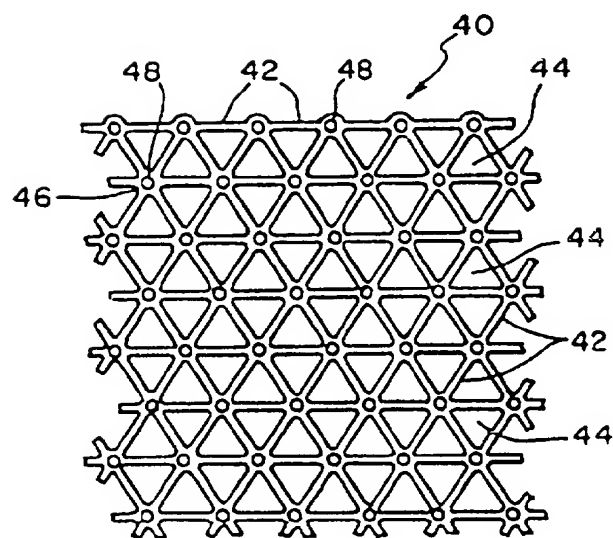


FIG. 5.



INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 97/07196

A. CLASSIFICATION OF SUBJECT MATTER

IPC 6 A61B17/80

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 6 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	DE 41 11 856 C (OSWALD LEIBINGER) 16 July 1992 see abstract; figures 2-5 see column 3, line 13 - column 4, line 8 ---	1
X	DE 90 14 613 U (OSWALD LEIBINGER) 31 January 1991 see page 1, line 9 - line 11 see page 10, line 34 - line 36 see page 11, line 4 - line 6 see page 11, line 25 - line 28 see page 12, line 32 - line 34 see figure 4 --- -/-	1-9

☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

* Special categories of cited documents :

- *A* document defining the general state of the art which is not considered to be of particular relevance
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- *T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- *X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- *Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- *&* document member of the same patent family

Date of the actual completion of the international search

4 August 1997

Date of mailing of the international search report

14. 08. 97

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Nice, P

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 97/07196

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5 139 497 A (D.M.TILGHMAN AND F.H.MORGAN) 18 August 1992 see abstract; figure 1 see column 3, line 16 - line 24 see column 3, line 52 - line 57 ---	1-3,8,9
A	EP 0 566 255 A (TIMESH) 20 October 1993 see column 2, line 55 - column 3, line 37 see column 5, line 39 - line 43 ---	1-3
A	EP 0 290 138 A (R.A.POLLOCK) 9 November 1988 see abstract; figure 1 -----	1

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 97/07196

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: 10
because they relate to subject matter not required to be searched by this Authority, namely:
PCT Rule 39.1 (iv) Method for treatment of the human or animal body by surgery
2. ☐ Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/US 97/07196

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